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RESEARCH ARTICLE

TRENDS IN PRESCRIBING PATTERN OF INSULIN PREPARATIONS AMONG UNCONTROLLED TYPE 2 DIABETES MELLITUS PATIENTS

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ABSTRACT

Background: Type 2 diabetes mellitus (T2DM) is a progressive disorder of β-cell dysfunction until majority of patients with a longer duration of diabetes remain poorly controlled with oral agents, and use of insulin, which could improve glycemic control .Guidelines from the American Diabetes Association and the European Association for the Study of Diabetes recommend that insulin secretagogues such as sulfonylureas be discontinued at the time of insulin initiation to reduce the risk of hypoglycemia, and that treatment be intensified if HbA1c levels remain above-target 3 months after insulin initiation.

Study design and methods: It was a prospective study and patients diagnosed with T2DM initiating insulin and no prior insulin use. The study duration was six months (December 2016 to May 2017) among type 2 diabetes mellitus patients at Karuna Medical College and Hospital, Diabetic centre, Quality clinic-Palakkad.

Result and Discussion: Out of total 308 study populations, 226(73.37%) were taking Human insulin, 82(26.62%) were taking Insulin analogues.

Conclusion: Human insulin dominate the prescribing pattern, but there was a shifting trend towards the use of insulin analogue preparations in the management of Type 2 diabetes mellitus. In achieving optimal glycemic control, intensification of current insulin treatment as well as planning multiple drug interventions with lifestyle modification is necessary.

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INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a progressive disease in which poor glycemic control is exacerbated over time and pancreatic b-cell function declines (Kanatsuka *et al*., 2014). It is estimated that by the year 2030, over 70% of people with diabetes will reside in developing countries (Ogbera *et al*., 2012). While treatment algorithms developed by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) recommend metformin as the initial choice for patients with type 2 diabetes, over time, many patients will require intensification of therapy with medications including insulin (Patrick *et al*., 2013). The (United Kingdom Prospective Diabetes Study) UKPDS showed that about 30% of patients taking sulphonylureas and 22% of those taking metformin required insulin within 6 years because oral agents failed to maintain control (Ogbera *et al*., 2012). The 2006 and 2009 ADA/EASD guidelines recommend that metformin treatment be followed by the addition of basal insulin or a sulfonylurea as secondstep therapy if HbA1c levels remain ≥ 7 % after 2–3 months; the guidelines were updated in 2012 to include dipeptidyl peptidase-4 (DPP-4) inhibitors, GLP-1 receptor agonists, and thiazolidinediones as alternative second-step therapies, and to include regimens of twice daily pre-mixed insulin or basal plus mealtime insulin as initial insulin regimens for patients with severely elevated HbA1c levels. If HbA1c levels remain ≥7% after another 3 months, the initiation or intensification of insulin is recommended as a third treatment step. Because insulin secretagogues such as sulfonylureas and meglitinides increase the risk of hypoglycemia, the ADA and EASD recommend that these agents be discontinued at prandial insulin initiation (Patrick *et al*., 2013). Therefore, most of the patients with T2DM will require insulin treatment due to eventual loss of insulin secretion (Joshi *et al*., 2009). Insulin therapy is used in the management of diabetes mellitus of all types and the need for insulin depends on the balance between insulin secretion and insulin resistance. The evidence of early insulin treatment lowering macrovascular (coronary artery disease, peripheral arterial disease and stroke) and microvascular (diabetic nephropathy, neuropathy and retinopathy) complications of

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T2DM (Sanlioglu *et al*., 2013). Therefore, this study aimed at analyzing prescribing trends of insulin preparations among patients with T2DM in tertiary care hospitals at Palakkad.

MATERIALS AND METHODS

This was a prospective, observational study carried out in Diabetology and Medicine Department of a Tertiary Care Hospitals in Palakkad. The sample size for this study was 308 patients in accordance with Ethics committee manual to assess drug use in individual facilities. It was a pilot study with duration of 6 months (December 2016 to May 2017) in which 308 patients of Type 2 diabetes mellitus (T2DM) of receiving Insulin therapy was randomly selected for participation after fulfilling inclusion/exclusion criteria. Patients with T2DM and treated with initiating insulin like Insulin Glargine, Premixed insulin (70% NPH/30%RI, 50%NPH/50%RI or NPH plus either Lispro or Aspart in a ratio of 70/30 or 75/25) and no prior insulin use were included in the study. After obtaining informed consent, sociodemographic data along with details of insulin therapy, duration of DM and life style modifications (dieting/exercise/both) was recorded. We excluded Patients with cognitive impairment, visual or hearing loss, T1DM, women with current or anticipated pregnancy, patients not willing for informed consent. The following parameters were analyzed: Average number of Basal and Bolus Insulin cases per prescription, percentage of different class of Basal and Bolus Insulin prescribed, commonest class and type of Insulin prescribed, pattern of insulin use, percentage of previous history of OHA(S)among study populations were analyzed.

RESULTS

Three hundred and eight (n = 308) patients of Type 2 diabetes were analyzed. Male were 40.25% (n = 124), female were 59.74 % (n = 184) in the study.

Prescribing pattern

During the study, the prescribing pattern of insulin varied from person to person. Prior to insulin treatment, 254 (82.46%) of the study subjects were on oral hypoglycaemic agents. With insulin treatment, the pattern of treatment was such that of the patients with type 2 DM, 250 (81.16%) were on combinations of insulin and oral hypoglycaemic agents and 58 (18.8%) were on sole insulin treatment. Out of total 308 prescribed Insulin therapy, 226(73.37%) were taking Human insulin, 82(26.62%) were taking Insulin analogues (Table 3). From that 209(67.85) were receiving Fixed dose combinations (FDC) (30/70, 50/50). Human Insulin was the commonly used insulin with premixed preparations taking the lead. The pattern of insulin use is shown in Table 3. Fixed dose combinations (73.37%) were the most commonly prescribed class followed by Insulin analogues (26.62%) among the different classes of insulin (Table 3). Inj.Glargine (Insulin analogues) was the most common to be prescribed 20.45%, followed by regular insulin (Human insulin) 5.5%, followed by Inj. Aspart 4.2% (Table 3). FDC prescribed were include insulin isophane (NPH) (50%) + insulin regular (50%), insulin regular, insulin isophane (NPH) (70%) + Insulin regular (30%) respectively. Hypoglycaemia was the most frequently documented problems encountered by persons on insulin.

Table 1. Clinical characteristics of study subjects

S.No	Characteristics	Number of Patients (%)
1	Gender	
	Female	184(59.74)
	Male	124(40.25)
2	Age	
	40-49 years	26(8.4)
	50-59 years	81(26.29)
	60-69 years	117(37.98)
	70-79 years	61(19.80)
	≥80 years	14(4.5)
3	Social Habits	
	Smoking	26(8.4)
	Alcoholic	46(14.9)
4	Obesity	21(6.81)
5	Duration of DM (yrs)	
	<5	18(5.8)
	6-10	74(24.02)
	11-20	111(36.03)
	21-30	49(15.90)
	31-40	6(1.9)
	>41	3(0.97)

Table 2. Distribution of previous history of OHA(s) among study population

OHA(s)	Number of patients (n= 308)	Percentage (%)
Metformin	52	16.8
Glimepiride	47	15.2
Glipizide	1	0.32
Glibenclamide	5	1.6
Acarbose	1	0.32
Voglibose	12	3.89
Pioglitazone	19	6.16
Sitagliptin	1	0.32
FDC (Glimepiride +Metformin)	55	17.85
FDC (Metformin +Glibenclamide)	48	15.58
FDC (Sitagliptin +Metformin)	4	1.2
FDC (Gliclazide +Metformin)	7	2.27
FDC (Gliclazide +Metformin +Pioglitazone)	2	0.64

FDC- Fixed Dose Combination

Table 3. Pattern of insulin use

Type of insulin use	N (%)
Human insulin (N=226)	
Fixed Dose Combinations (30/70,50/50)	209(67.85)
Regular insulin	17(5.5)
Insulin Analogues (N=82)	
Inj.Glargine	63(20.45)
Inj.Aspart	13(4.2)
Inj.Lispro	6(1.94)

Table 4. Prescribing frequency of Insulin in study populations

Anatomical therapeutic chemical group	N=308 (%)
Monotherapy Insulin	58(18.8)
Combination therapy	
Insulin+Metformin	62(20.12)
Insulin+Glimepiride	51(16.55)
Insulin+Pioglitazone	1(0.32)
Insulin+Glipizide	1(0.32)
Insulin+(Glibenclamide+Metformin)	96(31.16)
Insulin+(Sitagliptin+Metformin)	15(4.87)
Insulin+(Gliclazide+Metformin)	15(4.87)
Insulin+(Glimepiride+Metformin)	9(2.92)
Total	308

DISCUSSION

In this study, an attempt has been made to describe the current prescribing pattern and trend of insulin therapy along with the efficacy of anti-diabetic drugs in maintaining an optimal

glycemic level in diabetic patients in tertiary care hospitals at Palakkad. The role of insulin in the management of diabetes mellitus cannot be overemphasized and people with diabetes, use combinations of different types of insulin to better control and manage their condition (King *et al*., 1998; Makame *et al*., 1992). In this Report, we note that the majority of persons with type 2 DM who are on insulin therapy use insulin in varying combinations only or with oral glucose lowering agents. A third of the respondents reported omitting insulin injections with the commonly documented reason for this being the associated high costs of insulin. Often described barriers to use of insulin include fear of injections and hypoglycemic events, burden of injections, inconveniences associated with its use (Anderson *et al*., 2003). The combination of prandial and basal insulin clearly results in better glycaemic control and less glucose variability (Malone *et al*., 2005). Multiple insulin dosing administration commencement in our patients with DM depends on the degree of hyperglycemia and the patient's acceptance of multiple daily injections. Professional diabetes organizations recommend that basal or premixed insulin could be used as the initial insulin therapy. The basal insulin analogue glargine has a long duration of action, with little or no discernible peak in blood insulin concentration, and a lower rate of hypoglycemia (Zhang *et al*., 2014). Premixed insulin formulations are prescribed for many patients with T2DM because of their proven efficacy in improving glycemic control, fewer daily injections, and better postprandial glucose control compared with basal insulin regimens (Bellido *et al*., 2015). The most commonly prescribed preparation was premixed insulin preparation. We found a higher percentage of insulin prescribing and insulin based therapy in our study compared with previous Indian studies. Insulin preparations can provide intensive, near‐physiologic delivery of insulin and can help patients achieve better glycemic control (Rajeswari *et al*., 2007; Sutharson *et al*., 2003). This reflects a change in prescribing trend and shift toward insulin based therapy from the dominated class of OHA in Type 2 diabetes treatment (Shah *et al*., 2009). The most prevalent anti‐diabetic therapy was monotherapy either with OHA or insulin, while combination therapy with OHA's and insulin was to a lesser extent.

Conclusion

There was no individualization of doses according to age group, particularly in elderly patients. It was possible to estimate the use of insulin that may contribute to improving issues related to drug management. Therefore, the database enabled the analysis of drug therapy, drug doses, drug management, and prescription failures being valuable tools for the pharmacist to investigate prescription profiles, contributing to patient care.

REFERENCES

Anderson EA *et al*. 2003. Understanding and enhancing adherence in adults with diabetes. *Curr Diabetes Reports*, 3:141–148.

Bellido V *et al*. 2015. Comparison of Basal-Bolus and Premixed Insulin Regimens in Hospitalized Patients with Type 2 Diabetes. *Diabetes Care*, Dec;38(12):2211-2216

Joshi S *et al*. 2009. A review of insulin and insulin regimens in type 2 Diabetes, *South African Family Practice*, 51:2, 97-102

Kanatsuka A *et al*. 2014. Evaluation of insulin regimens as an effective option for glycemic control in patients with type 2 diabetes: A propensity score-matched cohort study across Japan (JDDM31), *J Diabetes Invest*, 5: 539–547

King H *et al*. 1998. Insulin: availability, affordability, and harmonization. *WHO Drug*, 4:219–223

Makame MH *et al*. 1992. Childhood Diabetes, Insulin, and Africa. *Diabet Med*., 9:571–573.

Malone JK *et al*. 2005. Twice-daily pre-mixed insulin rather than basal insulin therapy alone results in better overall glycemic control in patients with type 2diabetes. *Diabet Me*d., 22:374–381.

Ogbera A *et al*. 2012. Insulin use, prescription patterns, regimens and costs.-a narrative from a developing country, *Diabetology & Metabolic Syndrome*, 4:50

Patrick A *et al*. 2013 Trends in Insulin Initiation and Treatment Intensification Among Patients with Type 2 Diabetes, *J Gen Intern Med*., 29(2):320–7

Rajeswari S *et al*. 2007. Drug utilisation study in geriatric type 2 diabetic patients. *J Clin Diagn Res*., 1:440‐3

Sanlioglu A *et al*. Clinical utility of insulin and insulin analog. Islets. 2013 Mar 1; 5(2): 67–78

Shah S *et al*. 2009. Base line characteristics of the Indian cohort from the IMPROVE study: A multinational, observational study of biphasic insulin aspart 30 treatment for type 2 diabetes. *Adv Ther*., 26:325‐35.

Sutharson L *et al*. 2003. Drug utilization study in diabetology outpatient setting of a tertiary hospital. *Indian J Pharmacol*., 35:237‐40.

Zhang Y *et al*. 2014. Clinical study of treatment switching from premixed insulin to basal insulin combined with oral hypoglycemic drugs in patients with T2DM, *Diabetol Metab Syndr*., Mar 13;6(1):37

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